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DISINFECTION AND DECONTAMINATION HANDWASHES BASED ON NATURE-IDENTICAL AROMATIC ALCOHOLS

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(57) Claim

1. An aqueous disinfection and decontamination handwash which comprises
 - a) from 5 to 35 wt.% of a C₁-C₁₉ alkyl alcohol,
 - b) from 0.1 to 10.0 wt.% of a naturally occurring C₆ aryl C₁-C₈ alkyl alcohol
 - c) from 0.5 to 45 wt.% of a sulphosuccinate, a betaine or a fatty alcohol ether sulphate or a mixture thereof, and
 - d) from 0.1 to 5.0 wt.% of a skin-compatible α -hydroxy carboxylic acid,the pH value of said handwash ranging from 2 to 7.

9. A method for disinfection and decontamination of hands which comprises washing the hands in an aqueous solution comprising
 - a) from 5 to 35 wt.% of a C₁-C₁₉ alkyl alcohol,
 - b) from 0.1 to 10.0 wt.% of a naturally-occurring C₆ aryl C₁-C₈ alkyl alcohol,
 - c) from 0.5 to 45 wt.% of a sulphosuccinate, a betaine or a fatty alcohol ether sulphate or a mixture thereof, and
 - d) from 0.1 to 5.0 wt.% of a skin-compatible α hydroxy carboxylic acid,said solution having a pH ranging from 2 to 7.

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Invention Title:

**DISINFECTION AND DECONTAMINATION HANDWASHES BASED ON
NATURE-IDENTICAL AROMATIC ALCOHOLS**

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The following statement is a full description of this invention, including the best method of performing it known to applicant(s):

DISINFECTION AND DECONTAMINATION HANDWASHES BASED ON
NATURE-IDENTICAL AROMATIC ALCOHOLS

The importance of hand disinfection for the purposes of preventing nosocomial infections in hospitals and medical practices has been undisputed since
5 Semmelweis.

In the pharmaceutical industry and the food industry hand disinfection and decontamination above all have the object of preventing possible contamination of the manufactured products by undesirable germs. For the treatment of hands, preparations are frequently used in this field which clean and
10 disinfect at the same time. Such preparations are nowadays known under the name "disinfection and decontamination handwashes".

Through the rinsing of hands after the cleaning and disinfection or decontamination process, product constituents ultimately enter the waste water. The issue of their biological degradation is also therefore of great significance for
15 the protection of the environment.

The aqueous hand disinfectant described in patent specification DE 31 17 792 C3 contains as essential active ingredient 2-^{phenyl}~~phenyl~~phenol. Although this phenol is in itself easily degradable, it can however not be ruled out that it is converted in chlorine-containing waste water to a polychlorophenol which is
20 difficultly degradable.

Phenols - 2-phenylphenol included - are increasingly rejected for use as hand decontamination agents because it cannot be ruled out with absolute certainty that, in practice, traces of the phenol are transferred to the manufactured pharmaceuticals and foods.

Also known, from DE-AS-11 05 549, are disinfecting washing and
25 cleaning agents which contain a mixture of free lactic acid with other disinfection agent active ingredients such as aldehydes, phenols or mercury compounds, surface-active, acid-resistant anionic, non-ionic, cationic or ampholytic substances. These agents are however likewise questionable or not acceptable from a drug-
30 and food laws point of view or undesirable from an ecological standpoint.

A known and highly effective process for hand disinfection consists in rubbing into the hands alcohols such as ethanol, isopropanol or n-propanol or a mixture of same. This process is not suitable in practice if the hands are visibly contaminated with all types of dirt, as is often the case in e.g. pathology and the
35 food industry.

Outside the German-speaking area, the disinfection handwash is in any case still preferred over the rubbing-in method.

In establishing the future methods for testing hand disinfection agents in Europe, the CEN (Comité Européen de Normalisation: European
5 Committee for Standardization) considered this procedure and thereupon suggested a new test method for disinfection handwashes (hygienic handwash).

It is therefore desirable that disinfection handwashes satisfy not only the conditions of hand decontamination, as are stipulated in the food industry, but also these new requirements of the CEN method.

10 Mixtures of surfactants and the alcohols ethanol, isopropanol and n-propanol satisfy both test conditions if the proportion of these alcohols is greater than 45 wt.%. These surfactant-alcohol mixtures are however poorly skin compatible.

It is therefore a desired feature of the invitation to meet the conditions of
15 the CEN method and of hand decontamination with a disinfection handwash which distinguishes itself by a high skin compatibility and contains no phenolic active ingredients.

The present invention resides in an aqueous disinfection handwash which comprises

- 20 a) 5 to 35, preferably 10 to 30 wt.% C₁-C₁₉ alkyl alcohol,
b) 0.1 to 10.0, preferably 0.5 to 5.0 wt.% naturally occurring C₆-aryl-C₁-C₈ alkyl alcohol,
c) 0.5 to 45, preferably 0.5 to 15 wt.% sulphosuccinate, betaine or fatty alcohol ether sulphate or a mixture of same and
25 d) 0.1 to 5.0, preferably 0.1 to 3.0 wt.% of skin-compatible α -hydroxy carboxylic acid the pH value of said handwash ranging from 2 to 7.

Throughout the description and claims of this specification, the word "comprise" and variations of the word, such as "comprising" and "comprises", is not intended to exclude other additives,
30 components, integers or steps.

Preferred embodiments are the subject of the dependent claims.

Preferred as C₁-C₁₉ alkyl alcohol, preferably C₁-C₁₂ and especially C₁-C₆ alkyl alcohol are compounds such as ethanol,
35 isopropanol or n-propanol or a mixture of same.

The C₆-aryl-C₁-C₈-alkyl alcohols are those with unbranched alkyl groups and preferably C₆-aryl-C₁-C₆ alkyl alcohols and especially C₆ aryl-C₁-C₃ alkyl alcohols such as benzyl alcohol, phenyl ethyl alcohol, phenyl propyl alcohol or a mixture of same.

α -Hydroxycarboxylic acids preferred according to the invention are lactic acid and mandelic acid.

The sulphosuccinate is preferably the disodium salt of sulphosuccinic acid lauryl ester, whereby one COOH group is esterified and the other COOH group and the SO_3H group are present as anion (salt form), with 1 - 4 EO (ethylene oxide units), the betaine is preferably cocamidopropyl betaine or lauryl betaine and the fatty alcohol ether sulphate is preferably sodium lauryl ether sulphate, magnesium lauryl ether sulphate, ~~monoethanolamine~~ ^{monoethanolamine} ether sulphate or ammonium lauryl ether sulphate or a mixture of the same, each with 1 - 6 EO. The pH value of the solution is preferably in the range from 3 to 6.

It is surprising that this combination of selected components, each of which when used alone shows no adequate action or shows an effect only at substantially higher use concentrations, leads to an agent which both satisfies the new conditions of the CBN method as well as those of hand decontamination and which in addition distinguishes itself by an excellent skin compatibility and good biological degradability.

It is also advantageous that the alcoholic active ingredient base consists exclusively of alcohols which occur naturally and whose toxicological properties are adequately known.

Other auxiliaries can be added to the mixtures used according to the invention, e.g. skin protection substances such as allantoin in a quantity of preferably 0.1 to 0.3 wt.%, so-called reverse fats such as polyol fatty acid esters or lauryl alcohol with 2 EO in a quantity of preferably 0.5 to 3.0 wt.%, thickening agents such as hydroxyethyl cellulose or their derivatives in a quantity of preferably 0.5 to 2.0 wt.%, dyes in a quantity of preferably 0.001 to 0.1 wt.% or perfumes in a quantity of preferably 0.05 to 1.0 wt.%. The quantities are in each case quoted relative to the total mixture.

The following base formulations A to C can for example be used as disinfection solution:

Formulation A

15	wt. %	1-propanol	
12	wt. %	2-propanol	
2	wt. %	2-phenylethyl alcohol	
5	10	wt. %	disodium salt of sulphosuccinic acid lauryl ester with 1 - 4 EO
3	wt. %	cocamidopropyl betaine	
0.5	wt. %	lactic acid	
	remainder	water	

10

Formulation B

	10	wt. %	1-propanol
	8	wt. %	2-propanol
	2	wt. %	3-phenylpropanol-1
15	1	wt. %	disodium salt of sulphosuccinic acid lauryl ester with 1 - 4 EO
	9	wt. %	sodium lauryl ether sulphate with 1 - 6 EO
	0.5	wt. %	lactic acid
	remainder		water

20

Formulation C

	10	wt. %	1-propanol
	8	wt. %	2-propanol
	2	wt. %	3-phenylpropanol-1
25	1	wt. %	disodium ^{salt} of sulphasuccinic acid lauryl ester with 1 - 4 EO
	9	wt. %	sodium lauryl ether sulphate with 1 - 6 EO
	1	wt. %	mandelic acid
	remainder		water

30

The hand disinfection and decontamination agents according to the invention are produced by dissolving the aryl alkyl alcohol in the alkyl alcohol at room temperature. The other components are then added, the acid being added at the end.

35

The effectiveness of these agents was tested according to both the new CEN methods and the known method of hand decontamination.

Hygienic handwashing according to CEN

1. Requirements

- 5 The average reduction in microorganisms by treating the hands with a product for the hygienic washing of hands must be significantly greater than the germ reduction which is achieved with the reference solution (Sapo Kalinus, Eur. Pharm, 20 % wt./vol.). The application time must not exceed 60 seconds. The reduction factors are ascertained from the differences of the starting and finishing values, usually expressed by the common logarithm:

$$\log RF = \log \text{starting value} - \log \text{finishing value}$$

10 2. Subjects

15 subjects with healthy skin and short fingernails are needed for this experiment.

3. Test organism

- 15 The standard test organism is Escherichia coli ATCC 11229. E. coli is cultivated in two tubes each with 5 ml CS solution (CSL; casein peptone soya bean flour peptone solution; nutrient medium for cultivating bacteria) for 18 to 24 hours at 36°C. The contents of these tubes are then added in each case to 1 l CS solution and again incubated for 18 to 24 hours at 36°C ± 1°C. The two suspensions are then mixed (= 2 l total volume). The germ count should be 2 x 10⁸ to 2 x 10⁹ CFU/ml (colony-forming units per ml).

4. Contamination of the hands

- 25 The hands are washed for 1 minute with the reference solution (Sapo Kalinus, 20 wt. %/vol.) and then immediately dried with paper hand-towels. The hands are then dipped for 5 seconds into the germ suspension and dried in the air (3 minutes). After the drying of the hands, the starting values are determined.

5. Hand washing with the reference solution (R)

- 30 5 ml Sapo Kalinus are placed in the moistened hands which have to be washed according to a definite procedure. For this the following washing steps are carried out, whereby each of these steps includes 5 to-and-fro movements and the hands are alternated if necessary. Firstly, the palms of the hands are rubbed together. The palms of the one hand are then rubbed on the back of the other hand. Next, the palms of the hands are again rubbed together, the fingers of both hands this time being interlaced. The backs of the fingers of the one hand are then rubbed against the palm of the other hand, the fingers of the two hands being hooked into one another. Also, the thumb of the one hand is gripped by the other hand and rubbed by means of rotational movements against the palm of the hand

forming the fist. Finally, the interlocked fingers of the one hand are moved to-and-fro in rotary manner in the palm of the other hand. After exactly 60 seconds, the hands are rinsed. The final values are then determined.

6. Hand washing with the test solution (P)

- 5 This procedure is carried out in accordance with the instructions above for the reference solution. The average value of the log reduction factors of the test preparation must be significantly better than the average value of the log reduction factors of the reference solution Sapo kalinus.

7. Significance test

- 10 To test the significance, the Wilcoxon-Test for the paired comparison of connected random samples (significance level: $P = 0.01$) was used with one-sided formulation of the question.

Table 1

Statistical, pairwise comparison of the log Rf values
(Wilcoxon test) ascertained at R and P

15

Subject	P	R	P-R	Ranking by Difference	Ranking with Sign
1	3.98	3.33	0.65	11	11
2	3.21	2.68	0.53	8	8
3	4.38	2.90	1.48	15	15
4	3.34	2.77	0.57	9	9
5	3.55	2.70	0.85	14	14
6	3.60	2.83	0.77	13	13
7	2.79	2.52	0.27	6	6
8	2.72	2.73	- 0.01	1	1
9	2.69	2.80	- 0.11	3	- 3
10	3.26	2.57	0.69	12	12
11	3.11	2.87	0.24	4	4
12	2.61	3.03	- 0.42	7	- 7
13	2.49	2.23	0.26	5	5
14	3.21	2.63	0.58	10	10
15	3.25	3.30	- 0.05	2	- 2

Rankings total (+) = 107

Rankings total (-) = 13

T = 13 (smaller rankings total)

The smaller rankings total ($T = 13$) is compared with the value given in Table 2 for 15 pairs and a significance level of 0.01 (here 19). If T is smaller than the value in the table, P is significantly better than R .

Table 2

- 5 Sign test for pair differences according to Wilcoxon Significance limits for the smaller ranking totals with identical signs (T) with one-sided formulation of the question

n (number of pairs with a difference $\neq 0$)	Significance level		
	0.05	0.01	0.001
12	17	9	2
13	21	12	4
14	25	15	6
15	30	19	8

Instructions for the sign ranking test:

1. The difference of each value pair is determined.
- 10 2. Regardless of the sign, the differences are ranked according to their absolute size.
3. The sign of the corresponding difference value is added to each ranking number.
- 4 The totals of the (+) rankings and the (-) rankings are formed.
- 15 5. The number of pairs whose difference does not equal 0 is determined ($= n$).
6. In Table 2 the table value is looked up in line n and column 0.01. If the smaller rankings total T is the same size as or smaller than the table value, the average log R_f of P is significantly greater than that of R .

Hand decontamination

- 20 Experiments under conditions which resemble those met in practice (Zbl. Bakt. Hyg. B 182, 562 - 570:1986).

Principle

- 25 The reduction in the germ release from the finger tips of an artificially contaminated hand serves as a measure of the effect in the test reflecting conditions met in practice. The size of this reduction results from the ratio of the quantities of germs which are released from the finger tips into a collecting liquid before and after decontamination of the hands.

Subjects (= PR)

- The experiments are carried out with 20 different PR. The values of at least 18 PR must be available for evaluation; if the standard deviation accounts for more than 50 % of the mean value of the rates of reduction, the number of PR's is to be increased in a further test. People with severe hyperkeratosis, skin injuries and long fingernails are not suitable.

Test germ

Escherichia coli ATCC 11229

Contamination

- After washing the hands with a non-antimicrobially acting soap under running hand-hot water for 2 minutes, the hands are dried with disposable hand towels. Afterwards, they, including thumbs, are dipped as far as the middle of the metacarpus for 5 seconds into a suspension of E. coli which has been prepared by incubating the test germ for 24 hours in 2 l CS solution at 37°C. The suspension must contain at least 10^8 CFU/ml, which is to be demonstrated by a quantitative surface structure on CSA. After being allowed to drip for a short time, the hands are held horizontal for 3 minutes to dry in the air, whereby drops are to be prevented from forming by spreading the fingers and rotating them slowly back and forth.

Decontamination procedure

Determination of the released CFU prior to hand decontamination = Starting values (SV):

- For the determination of the number of CFU which the finger tips of the contaminated hands release prior to decontamination, the tips of fingers 1 - 5 of each hand are dipped into a plastic Petri dish (diameter ca. 9 cm) filled with 10 ml collecting liquid (CSL + inactivating substances) and kneaded out on the floor of the dish with crossing and rubbing movements for 1 minute. 0.1 ml from each of 1:1000 and 1:10000 dilutions in CBL ~~inactivating~~ ^{- inactivating} substances - of this collecting fluid are spread by a spatula onto CSA (with the addition of 0.05 % Na-desoxycholate).

Hand decontamination follows. The action of the decontamination agent shall be 30 seconds. The hands are then carefully rinsed for exactly 15 seconds under running hand-hot tap water.

- Determination of the released CFU after hand contamination final values (FV):

The procedure for establishing how many CFU of the test germ the finger tips of the contaminated hands still release after application of the decontamination procedure is analogous to that for establishing the starting value. Since now, however, lower values are to be expected, the portions of 0.1 ml of the undiluted collecting liquid and 0.1 ml of a dilution of 1 : 10 (in CSL + inactivating substances) are spread by spatula onto CSA plates (with the addition of 0.05 % Na-desoxycholate).

During practical application, the preparation is lathered up with some water after the 30-second decontamination and used for hand cleaning.

10 Incubation

All counting plates are incubated aerobically for 48 hours at 37°C and then counted.

Evaluation of the results of the experiment under conditions resembling those met in practice

15 Principle:

A procedure for hand decontamination is considered suitable if, on average, it reduces the germ release by at least 3.5 powers of ten.

Results

20 The results of the experiment under conditions resembling those met in practice (CEN) are summarized in Table 1. After 60 seconds, action time, a germ reduction (3.21 log steps) was achieved. This was significantly better than the result of the reference solution. In the experiment using conditions resembling those met in practice according to DGHM guidelines for hand decontamination, the requirements were likewise satisfied (Table 2). After a rubbing-in time of 30
25 seconds, a germ reduction of 3.64 log steps was achieved.

Table 3

Determination of microbicidal effectiveness under conditions resembling those met in practice according to the method proposed by CEN

Subject No.	Reference Solution (R)			Test Solution (P)		
	SV	-	FV	=	RF	
1	6.58		3.25		3.33	
2	6.30		3.62		2.68	
3	5.29		2.39		2.90	
4	5.51		2.74		2.77	
5	5.88		3.18		2.70	
6	5.82		2.99		2.83	
7	6.06		3.54		2.52	
8	5.91		3.18		2.73	
9	5.85		3.05		2.80	
10	6.21		3.64		2.57	
11	6.09		3.22		2.87	
12	6.22		3.19		3.03	
13	5.51		3.28		2.23	
14	5.86		3.23		2.63	
15	5.85		2.55		3.30	

Ø 5.92 - 3.13 = 2.79 6.05 - 2.84 = 3.21

Action time = 60 sec;

- 5 Quantity: 5 ml; the hands were moistened beforehand.

P is significantly better than R.

Significance level = 0.01

Rankings total (-) = 13 < T = 19 (see Table 1)



Table 4

Determination of microbicidal effectiveness under conditions resembling those met in practice according to the DGHN guidelines for hand decontamination

Subject No.	Test Solution (P)			
	SV	-	FV	= RF
1	6.35		3.14	3.21
2	5.83		2.47	3.36
3	5.91		2.18	3.73
4	5.56		2.91	2.65
5	6.12		3.05	3.07
6	6.17		2.28	3.89
7	6.28		2.55	3.73
8	5.53		1.75	3.78
9	6.38		2.36	4.02
10	5.65		1.64	4.01
11	6.05		2.07	3.98
12	6.29		2.24	4.05
13	6.04		2.42	3.62
14	5.72		1.69	4.03
15	5.68		2.50	3.18
16	6.17		2.17	4.00
17	6.07		1.63	4.44
18	5.38		1.75	3.63
19	5.73		2.81	2.92
20	5.59		2.19	3.40

Ø 5.93 - 2.29 = 3.64

The invention has been described with particular reference to preferred embodiments thereof but it will be understood that variations and modifications can be effected within the spirit and scope of the invention.

The claims defining the invention are as follows:

1. An aqueous disinfection and decontamination handwash which comprises
 - a) from 5 to 35 wt.% of a C₁-C₁₉ alkyl alcohol,
 - 5 b) from 0.1 to 10.0 wt.% of a naturally occurring C₆ aryl C₁-C₈ alkyl alcohol
 - c) from 0.5 to 45 wt.% of a sulphosuccinate, a betaine or a fatty alcohol ether sulphate or a mixture thereof, and
 - d) from 0.1 to 5.0 wt.% of a skin-compatible α -hydroxy carboxylic acid,the pH value of said handwash ranging from 2 to 7.
- 10 2. A handwash according to claim 1 which comprises
 - a) from 10 to 30 wt.% of a C₁-C₁₉ alkyl alcohol,
 - b) from 0.5 to 5.0 wt.% of a naturally occurring C₆ aryl C₁-C₈ alcohol,
 - c) from 0.5 to 15 wt.% of a sulphosuccinate, a betaine or a fatty alcohol ether sulphate or a mixture thereof, and
 - 15 d) from 0.1 to 3.0 wt.% of a skin-compatible α -hydroxy carboxylic acid.
3. A handwash according to claim 1 or 2 in which
 - a) the alkyl alcohol is ethanol, isopropanol, n-propanol or a mixture thereof,
 - b) the naturally occurring C₆ aryl C₁-C₈ alkyl alcohol is benzyl alcohol, a phenyl ethyl alcohol, a phenyl propyl alcohol or a mixture thereof,
 - 20 c) the sulphosuccinate is the disodium salt of sulphosuccinic acid lauryl ester with from 1 to 4 ethylene oxide units; the betaine is cocoamidopropyl betaine, lauryl betaine or a mixture thereof; the fatty alcohol ether sulphate is sodium lauryl ether sulphate, magnesium lauryl ether sulphate, monoethanolamine ether sulphate or ammonium lauryl ether sulphate or a
 - 25 mixture thereof, each having from 1 to 6 ethylene oxide units; and
 - d) the α -hydroxycarboxylic acid is lactic acid or mandelic acid.
4. A handwash according to claim 1, which comprises
 - 15 wt.% 1-propanol,
 - 12 wt.% 2-propanol,
 - 30 2 wt.% 2-phenylethyl alcohol,
 - 10 wt.% disodium salt of sulphosuccinic acid lauryl ester with 1-4 EO,
 - 3 wt.% cocamidopropyl betaine, and

- 0.5 wt.% lactic acid.
5. A handwash according to claim 1, which comprises
- 10 wt.% 1-propanol,
- 8 wt.% 2-propanol,
- 5 2 wt.% 3-phenylpropanol-1,
- 1 wt.% disodium salt of sulphosuccinic acid lauryl ester with 1-4 EO,
- 9 wt.% sodium lauryl ether sulphate with 1-6 EO, and
- 0.5 wt.% lactic acid.
6. A handwash according to claim 1, which comprises
- 10 10 wt.% 1-propanol,
- 8 wt.% 2-propanol,
- 2 wt.% 3-phenyl propanol-1,
- 1 wt.% disodium salt of sulphosuccinic acid lauryl ester with 1 to 4 EO,
- 9 wt.% sodium lauryl ether sulphate with 1-6 EO, and
- 15 1 wt.% mandelic acid.
7. A handwash according to claim 1, wherein the pH value lies in the range from 3 to 6.
8. A process for the production of a disinfection and decontamination handwash according to claim 10 which comprises the successive steps of: dissolving the naturally
- 20 occurring C₆ aryl C₁-C₈ alkyl alcohol in the C₁-C₁₉ alkyl alcohol at room temperature, adding the sulphosuccinate, betaine and/or fatty alcohol components; and, as a last step, adding the skin-compatible α -hydroxy carboxylic acid component.
9. A method for disinfection and decontamination of hands which comprises washing the hands in an aqueous solution comprising
- 25 a) from 5 to 35 wt.% of a C₁-C₁₉ alkyl alcohol,
- b) from 0.1 to 10.0 wt.% of a naturally-occurring C₆ aryl C₁-C₈ alkyl alcohol,
- c) from 0.5 to 45 wt.% of a sulphosuccinate, a betaine or a fatty alcohol ether sulphate or a mixture thereof, and
- d) from 0.1 to 5.0 wt.% of a skin-compatible α -hydroxy carboxylic acid,
- 30 said solution having a pH ranging from 2 to 7.
10. A method according to claim 9 in which
- a) the alkyl alcohol is ethanol, isopropanol, n-propanol or a mixture thereof,

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DISINFECTION AND DECONTAMINATION HANDWASHES BASED ON
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Abstract

The invention relates to a disinfection and decontamination

5 handwash which is characterized in that it comprises an aqueous solution which
 comprises

- a) 5 to 35 wt.% C₁-C₁₉ alkyl alcohol,
- b) 0.1 to 10.0 wt.% naturally occurring C₆ aryl C₁-C₈ alkyl alcohol,
- 10 C) 0.5 to 45 wt.% sulphosuccinate, betaine or fatty alcohol ether
 sulphate or a mixture of same and
- d) 0.1 to 5.0 wt.% of a skin-compatible α -hydroxy carboxylic acid as
 skin-protection component and for adjusting to a pH value of 2 to
 7.